UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

GARY A. FORST and BONITA A. FORST,

Plaintiffs,

v. Case No. 07-CV-612

SMITHKLINE BEECHAM CORPORATION
d/b/a GLAXOSMITHKLINE,

Defendant.

ORDER

Plaintiffs Gary and Bonita Forst ("the Forsts") bring this products liability and personal injury action against Defendant Smithkline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"), the manufacturer of the drug Paxil CR® ("Paxil"). Their claims arise from Gary Forst's attempted suicide after beginning use of the prescription antidepressant. GSK has filed a motion seeking summary judgment based on federal preemption of the Forsts' state law tort claims. For the reasons set forth below, the court will deny the motion. The court will also address several pending motions regarding documents filed in connection with the motion for summary judgment.

BACKGROUND

Gary Forst ("Mr. Forst") began taking a prescription for the antidepressant medication Paxil in 2004. (Defendant's Proposed Findings of Fact, "DFOF" ¶ 1). Paxil is part of a wider class of antidepressants referred to as selective serotonin

reuptake inhibitors, or "SSRI's." (*Id*. at ¶ 3). Shortly after beginning his prescription for Paxil, Mr. Forst attempted suicide. (*Id*. at ¶ 2).

The Federal Food and Drug Administration (FDA) originally approved Paxil in 1992. Since that time, the agency has also approved a number of supplemental New Drug Applications (NDA's) for new therapeutic indications, as well as two additional NDA's. (DFOF at ¶ 21). As part of its submissions to the FDA, GSK included safety and efficacy information regarding Paxil. The agency's approvals involved review of this information and were also contingent upon FDA acceptance of Paxil's labeling and warnings. (*Id*. at ¶¶ 22-24). However, the FDA never required revisions to Paxil's labeling to include warnings about an increased risk of suicidality as part of its consideration or approval of the submissions. (*Id*. at ¶ 28).

In March and April 2006, two years after Mr. Forst's suicide attempt, GSK submitted additional information to the FDA that included the results of metaanalyses of Paxil studies in adults. (DFOF ¶ 49). Based on these analyses, GSK consulted with the FDA and proposed changes to Paxil's labeling. (*Id*. at ¶ 51). GSK submitted a Changes Being Effected (CBE) supplement, which proposed a label change stating, among other things, that a statistically significant increase in the frequency of suicidal behavior in adults with Major Depressive Disorder was shown in placebo-controlled trials of Paxil. (*Id*. at ¶ 52). The FDA reviewed the CBE supplement and notified GSK that the supplement was approvable. (*Id.* at ¶ 57). However, the FDA directed that instead of including Paxil-specific language changes

to its labeling, GSK should employ standardized, class-wide labeling applicable to all SSRI medications. (*Id.* at ¶¶ 58-59, 63).

STANDARD

Summary judgment is appropriate where the moving party establishes that there is no genuine issue of material fact and that the party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). "Material facts" are those facts which "might affect the outcome of the suit," and a dispute about a material fact is "genuine" if a reasonable finder of fact could find in favor of the nonmoving party. *See Anderson v. Liberty Lobby*, *Inc.*, 477 U.S. 242, 248 (1986). The party opposing summary judgment cannot simply rest on allegations or denials in its pleadings, but rather, it must also introduce affidavits or other evidence setting forth specific facts showing a genuine issue for trial. *Anders v. Waste Mgmt. of Wis.*, 463 F.3d 670, 675 (7th Cir. 2006). Finally, in conducting its review, the court views all facts and draws all reasonable inferences in favor of the nonmoving party. *Tanner v. Jupiter Realty Corp.*, 433 F.3d 913, 915 (7th Cir. 2006).

ANALYSIS

Three motions remain pending before the court, one for summary judgment and two regarding related filings. The court will address each motion in turn.

I. Summary Judgment Motion

GSK urges this court to enter summary judgment in its favor because federal law, in the form of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et. seq.*, preempts the Forsts' state law claims. Specifically, GSK asserts Paxil would

have been misbranded under FDA rules 21 C.F.R. § 352(a) and § 352(f)(1) if it had provided the enhanced warnings that the Forsts claim were required. Therefore, GSK concludes, federal and state law applies conflicting duties and trigger preemption of the state tort claims. However, since the time GSK filed its motion for summary judgment, the United States Supreme Court has addressed the precise preemption issue currently before this court. The Supreme Court decided *Wyeth v. Levine*, 555 U.S. ___, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009), a case involving state law failure-to-warn claims against a drug manufacturer. The defendant drug manufacturer in *Levine* raised the same arguments for preemption of state law claims arising from prescription drug labeling that GSK argues in its summary judgment brief. Thus, the *Levine* decision informs this court's resolution of the preemption issue and compels a denial of summary judgment.

In *Levine*, the plaintiff brought state law claims against the defendant drug manufacturer alleging that the company failed to provide an adequate warning about the risks of administering a particular drug, Phenergan, through an "IV push" method after she developed gangrene that required amputation of her forearm. *Id*. at 1189. Like GSK in the instant case, the defendant in *Levine* argued that the plaintiff's state law failure-to-warn claims were preempted because the manufacturer could not simultaneously comply with both state-law duties required by tort claims and federal labeling duties. *Id*. The drug manufacturer also argued that requiring it to comply with state law duties to provide stronger warnings would interfere with Congress' purpose of entrusting an expert agency with drug labeling decisions. *Id*. at 1190.

However, the Court rejected these arguments and held that the plaintiff's state law failure-to-warn claims were not pre-empted by federal law. *Id*. at 1189-90. Relying on the Supreme Court's holdings in *Levine*, this court similarly rejects GSK's preemption arguments.

When addressing preemption, the court starts with two guiding principles: 1) that the "purpose of Congress is the ultimate touchstone"; and 2) that a preemption analysis starts with the "assumption that the historic police powers of the States were not superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Levine*, 129 S. Ct. at 1194 (citations omitted). The court applies these principles to GSK's pre-*Levine* arguments that the Forsts' state law claims conflict directly with FDA-mandated labeling, that the state law claims interfere with Congress' purposes in regulating drugs, and that the FDA's position on preemption requires deference. However, the court's job is simplified because the Supreme Court directly addressed and rejected each of GSK's arguments.

GSK first argues that preemption applies because the company cannot simultaneously comply with its duties under both state and federal law. The Supreme Court found, however, that state law failure-to-warn claims do not directly conflict with FDA-mandated labeling because a drug manufacturer has both the ability and duty to update its warnings. *Levine*, 129 S. Ct. at 1198 (citing 21 CFR § 201.80(e); § 314.80(b); 73 Fed. Reg. 49605). Federal law does not prohibit drug manufacturers from updating their labels to warn of known risks when the FDA-approved labeling did not include the updated language. Instead, a drug

manufacturer has a duty to advise consumers of risks because it "bears responsibility for the content of its label at all times." *Id*. at 1197. Thus, a drug is not misbranded under the FDCA simply because a drug manufacturer modifies a previously-approved label by including enhanced warnings. *Id*. at 1197. Even if the addition of enhanced warnings did constitute "misbranding," drug manufacturers are not forced to choose between state tort liability or FDA enforcement action, as GSK implies. The Supreme Court dismissed possible agency enforcement against stronger drug warnings as a non-existent threat. *Id*. ("And the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to the CBE regulation is difficult to accept."). State failure-to-warn claims do not subject GSK to conflicting state and federal duties requiring preemption.

GSK next argues that state law failure-to-warn claims create an impermissible obstacle to the accomplishment and execution of Congress' objectives in regulating drugs. This argument is similarly dispatched by *Levine*. Instead of hindering congressional objectives, the Supreme Court concluded that state law claims promote Congress' objectives in regulating drugs by serving as an additional oversight on safety and effectiveness. *Levine*, 129 S. Ct. at 1200. Further, Congress' decision not to enact an express preemption of state claims is an acknowledgment of the important role played by these claims. *Id*. ("If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year

history.")) State tort claims are harmonious with Congress' regulatory goals and do not compel application of preemption.

GSK also argues for deference to the FDA's opinion that failure-to-warn claims are preempted by its drug labeling regulations. However, the Supreme Court did not find the agency's statements to be determinative and neither does this court. Agency regulations with the force of law may preempt conflicting state requirements, but the court performs its own conflict determination in these instances. *Levine*, 129 S. Ct. at 1200-01. In *Levine*, the Supreme Court concluded that the FDA's opinion was inconsistent with the agency's historical view of common law tort suits and was at odds with Congress' intent. *Id*. at 1201-02. Therefore, the FDA's statements on preemption do not require deference.

As discussed, the Supreme Court directly rejected each of GSK's original preemption arguments. However, GSK offers modified arguments following the issuance of *Levine*, as it must. GSK now argues that the FDA would not have approved an enhanced warning regarding suicidality for Paxil's label even if GSK had proposed one. GSK further argues that the Forsts' state law claims pose a risk of "overwarning" because there is no association between Paxil and increased suicidality in adults. Despite GSK's refined arguments, it still fails to establish that preemption of the Forsts' state law claims is appropriate.

GSK correctly asserts that *Levine* does not render state law failure-to-warn claims immune to preemption in every case. Indeed, the Supreme Court left open the possibility that "some" state law claims may frustrate the achievement of

congressional objectives in the federal regulation of drug labeling. *See Levine*, 129 S. Ct. at 1204. However, a defendant drug manufacturer faces an exacting burden to establish preemption of state law claims because compliance with both state and federal requirements for drug labeling is not impossible "absent clear evidence that the FDA would not have approved a change" in the drug's labeling. *Id*. at 1198. This "impossibility preemption" is a "demanding defense" and cannot be established simply by showing that the FDA approved the label which was in place at the time of the plaintiff's injury. *Id*. at 1199.

GSK tries to provide "clear evidence" that the FDA would have rejected enhanced warnings for Paxil by pointing to the amount of interaction it had with the agency and the FDA's repeated review of Paxil's safety data. GSK implies that because the FDA never required an enhanced warning in the past, despite exhaustive and repeated review of SSRI safety issues, that the agency concluded such warnings were unwarranted and inappropriate. However, the court does not deem GSK's evidence sufficient to establish "impossibility preemption." First, the fact that the agency considered the association between all SSRI's and suicidality on a number of occasions between 1992 and 2004, the time of Mr. Forst's suicide attempt, does not establish that the FDA would not have approved a proposed change in Paxil's labeling. Further, the FDA's approvals of supplemental New Drug Applications for Paxil and repeated review of safety and efficacy data do not definitively show that the agency would preclude additional safety warnings. Finally, the fact that the FDA approved prior Paxil labeling without an enhanced warning

does not mean that the agency would oppose a request by GSK to include such a warning. *See Levine*, 129 S. Ct. at 1199 (...the mere fact that the FDA approved [the drug]'s label does not establish that it would have prohibited such a change.").

GSK does provide evidence that the FDA denied proposed label language in 2007, three years after Mr. Forst's suicide attempt. However, it does not meet the demanding "clear evidence" requirement. In denying the proposed language, the agency did not prohibit all enhanced warnings. Instead, the FDA merely required removal of Paxil-specific language from a particular portion of Paxil's label in favor of uniform class-wide labeling for all SSRI's. The agency's action did not preclude Paxil-specific language changes to other areas of the labeling or prevent GSK from pursing a label change through submission of a separate supplement. In addition, the cases which GSK cites to support its position – cases finding that federal law preempts state law failure-to-warn claims – were decided before issuance of *Levine* and rely upon the threat of possible federal enforcement action for "misbranding," a justification that *Levine* views with extreme skepticism.[1]

Finally, GSK offers a re-worked version of its argument that state law claims interfere with Congressional objections in the federal regulation of drugs. GSK

[1]GSK cites language from *Mason v. SmithKline Beecham Corp*., 546 F. Supp. 2d 618 (C.D. Ill. 2008), and *O'Neal v. SmithKline Beecham Corp*., 551 F. Supp. 2d 993 (E.D. Cal. 2008), and claims that the respective district court findings of preemption are in line with *Levine*. (GSK Reply Br. 6-7). However, the cited portions both refer to the potential for federal liability based on the addition of a proposed warning. *Mason*, 546 F. Supp. 2d at 626-27; *O'Neal*, 551 F. Supp. 2d at 1008-09. The Supreme Court refuted this reasoning and rejected possible federal enforcement as a justification for preemption of failure-to-warn claims. *Levine*, 129 S. Ct. at 1197. Further, the court in *Mason* relied extensively on the Third Circuit case *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3rd Cir. 2008), in reaching its conclusion. 546 F. Supp at 621-27 (court holds that the plaintiffs' claims are preempted based on the reasons "set forth in *Colacicco* and this Order"). The Supreme Court vacated and remanded *Colacicco* for further consideration in light of its decision in *Levine. Colacicco v. Apotex, Inc*., 129 S. Ct. 1578, 1578-79 (2009).

asserts that state law failure-to-warn claims require drug manufacturers to "overwarn" about risks the FDA finds to be unsubstantiated. These overwarnings discourage use of antidepressants by people who may benefit from the medications, undermining public health and contravening the intent of drug safety regulation. However, the Supreme Court countered similar arguments in *Levine*. The Court suggested that state law claims enhance the regulation process and advance safety goals, rather than posing a danger. *Levine*, 129 S. Ct. at 1199-1200 (stating that common law remedies "further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings."). State law litigation provides an additional oversight on drug labeling and helps flesh out which warnings are "substantiated" and necessary for the protection of consumers.

GSK's "overwarning" argument also assumes that the subject drug label warns of a non-existent risk. Otherwise, the label would warn of an actual danger and promote safety, clearly advancing the objectives of the FDA in regulating drugs. GSK argues that no association exists between Paxil and increased suicidality in adults, thus, any enhanced warning to this effect constitutes "overwarning." In making this assertion, GSK revisits an argument made in its previous motion for summary judgment on the merits of the Forsts' claims. However, in denying GSK's first motion for summary judgment, this court refused to find that Paxil does not increase suicidality as a matter of law. *Forst v. Smithkline Beecham Corp*., 602 F. Supp. 2d 960, 967 (E.D. Wis. 2009). Therefore, the court will not apply preemption and grant summary judgment based on an argument it previously rejected.

II. Additional Motions

In addition to GSK's summary judgment motion addressed above, the Forsts also filed two motions regarding documents supporting the parties' summary judgment briefs. The Forsts filed a motion to unseal documents, as well as a motion to strike evidence submitted by GSK. The court will grant the motion to unseal documents and deny the motion to strike.

A. Motion to Unseal Documents

The Forsts ask the court to unseal fifteen documents filed conditionally under seal in support of its summary judgment opposition brief. GSK opposes any unsealing of the documents and argues that they represent confidential commercial information. Specifically, GSK asserts that public disclosure of the communications between GSK and the FDA and deposition testimony regarding these communications and labeling submissions would aid GSK's competitors and bias the public against GSK. However, GSK faces a difficult task in establishing that documents filed in connection with a dispositive motion should be shielded from public view.

Indeed, the Seventh Circuit Court of Appeals looks unfavorably upon the sealing of such documents. Secrecy may be appropriate during the discovery phase of litigation, however, documents that influence a judicial decision are open to public inspection unless falling within a category of "bona fide long-term confidentiality." *Baxter Int'l, Inc. v. Abbott Labs*., 297 F.3d 544, 545 (7th Cir. 2002). Indeed, the

Seventh Circuit emphasized that maintaining a court record open to the public is vital in ensuring the credibility of the court system:

> What happens in federal courts is presumptively open to public scrutiny. Judges deliberate in private but issue public decisions after public arguments based on public records. The political branches of government claim legitimacy by election, judges by reason. Any step that withdraws an element of the judicial process from public view makes the ensuing decision look like fiat and requires rigorous justification.

Hicklin Engineering, L.C. v. Bartell, 439 F.3d 346, 348 (7th Cir. 2006). However, Federal Rule of Civil Procedure 26 allows for the protection of a "trade secret or other confidential research, development or commercial information" by the court "for good cause." Fed. R. Civ. P. 26(c)(1). To merit such protection of its documents from disclosure, GSK must establish that each individual exhibit constitutes confidential commercial information. *See Baxter Int'l*, 297 F.3d at 545. Specifically, GSK must show that disclosure of its confidential business information will result in a "clearly defined and very serious injury." *Andrew Corp. v. Rossi,* 180 F.R.D. 338, 341 (N.D. Ill. 1998) (citing *Culinary Foods, Inc. v. Raychem Corp*., 151 F.R.D. 297, 300 n.1 (N.D. Ill. 1993)).

The court considers whether there is good cause to seal documents regarding GSK's communications with the FDA and deposition testimony regarding these communications.[2] GSK argues that correspondence with the FDA is confidential because it is contained within Paxil's Investigational New Drug and New Drug

[2]GSK does not oppose the unsealing of Exhibit 27 to the Declaration of Bijan Esfandiari in Support of Plaintiffs' Opposition to GSK's Motion for Summary Judgment ("Esfandiari Decl."). (Docket #119). Therefore, the court will unseal the exhibit.

Applications (collectively, "NDA") and is, therefore, presumptively protected. GSK acknowledges that correspondence from a pharmaceutical manufacturer to the FDA is available for public disclosure, however, it maintains that confidential commercial information is exempted under 21 C.F.R. § 20.61.[3] (GSK Opp. Pls.' Mot. Unseal 5).

However, the Forsts' point out that Paxil's patent expired in 2006 and is now subject to generic competition. Therefore, generic manufacturers are encouraged to rely upon Paxil's safety and efficacy data, which is now open to the public, and any protections for NDA-related correspondence no longer apply. Indeed, a company marketing a generic version of Paxil can rely on the clinical studies performed by Paxil as the pioneer drug manufacturer. *SmithKline Beecham Corp. v. Apotex Corp*., 383 F. Supp. 2d 686, 690 (E.D. Pa. 2004). Paxil's safety and efficacy data are already available to generic drug manufacturers, who constitute actual "market competitors." Thus, it is difficult to see how release of this same information to the general public would cause serious injury or substantial competitive harm to GSK.

Further, GSK's explanations for why release of its documents would cause substantial competitive harm fail to establish the requisite good cause for sealing. GSK argues that it will suffer harm because disclosure will do the following: endanger the public health by providing conflicting information about Paxil's safety and efficacy; allow competitors to show "out of context snippets" of GSK

[3]The cited exemption in 21 C.F.R. § 20.61 defines confidential commercial information as follows: "valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs." 21 C.F.R. § 20.61(b).

correspondence to healthcare professionals and "bias" them against GSK; give competitors "insights into how GSK analyzes and interprets its clinical data"; allow competitors to use and/or exploit GSK's proprietary techniques for making labeling decisions in light of analyses of clinical trial data in their own dealings with the FDA; and, provide insight into GSK's "internal decision-making process." (GSK Opp. Pls.'s Mot. Unseal 7-8).

First, disclosure of additional safety and efficacy information about Paxil serves to promote public health rather than endanger it. Further, the fact that disclosure may allow competitors to paint Paxil in an unfavorable light to healthcare professionals is insufficient to render the information confidential. If litigation documents are sealable simply because they can be used to portray a company in an unflattering way, the public would have access to precious few. Next, communications with the FDA regarding Paxil's safety and efficacy data are already available because its patent has expired, allowing others to rely on this information. *See Cunningham v. Smithkline Beecham*, 2008 WL 2572076, at *4 (N.D. Ind. June 25, 2008) ("Smithkline also notes that unsealing the documents would permit public access to 'sensitive and confidential communications between GSK and FDA concerning the reporting on and submission of data collected from clinical trials of Paxil.' This, however, appears to be precisely the information that the FDA regulations make public once a drug's NDA no longer is pending."). Finally, asserting that disclosure provides insight into internal decision-making does not explain how competitors can obtain economic value from this information.

GSK fails to establish good cause for sealing either its correspondence with the FDA, or for sealing related deposition testimony. The court does not conclude that release of the information contained within the subject documents will result in a "clearly defined and very serious injury." See *Andrew*, 180 F.R.D. at 341. Therefore the court will grant the motion to unseal the subject documents.

B. Motion to Strike

The Forsts also move to strike evidence GSK submitted in support of its motion for summary judgment. The evidence falls into two categories: 1) *amicus* briefs filed in various pharmaceutical products liability cases by the FDA and a pharmaceutical organization; and 2) documents and petitions relating to a 1991 FDA advisory committee meeting regarding Prozac, another antidepressant. The Forsts request that the court strike this evidence, as well as any references or arguments based upon it.

The Forsts argue that striking the six *amicus* briefs is necessary because they are inadmissible hearsay, they represent incompetent evidence, they are undeserving of deference, and because consideration of the briefs violates the Forsts' due process right to challenge through cross-examination. However, the court finds the arguments unconvincing. As other courts have concluded, the *amicus* briefs filed by GSK do not constitute hearsay and, even if they did, they fall under the public records exception in Federal Rule of Evidence 803(8). *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 553, 572 n.3 (E.D. Pa. 2008); *O'Neal v. Smithkline Beecham Corp.*, 551 F. Supp. 2d 993, 1003 n.12 (E.D. Cal 2008).

Further, the court does not accept the Forsts' argument that the briefs are not competent because two specific FDA officials were not consulted in their generation. Next, the briefs need not be stricken simply because the FDA's position is undeserving of deference. Finally, the due process right to cross-examine is not implicated because the *amicus* briefs are not testimony.

The Forsts also urge the court to strike documents regarding a possible association between Prozac and suicide and documents regarding a 1991 Psychopharmacological Drugs Advisory Committee meeting as irrelevant. However, the documents are not wholly irrelevant simply because they involve Prozac, and not Paxil. The documents are sufficiently relevant because they address SSRI labeling and provide regulatory background on an earlier SSRI medication. Based on the foregoing, the court will deny the motion to strike.

Accordingly,

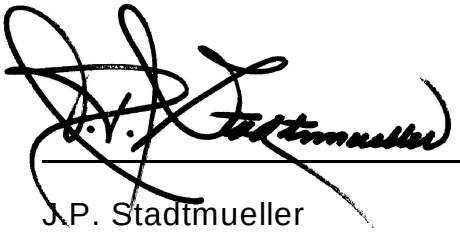
IT IS ORDERED that GSK's motion for summary judgment on the basis of federal preemption (Docket #35) be and the same is hereby **DENIED**;

IT IS FURTHER ORDERED that the Forsts' motion to unseal documents being filed conditionally under seal (Docket #123) be and the same is hereby **GRANTED**; the clerk of the court shall place in an open file Exhibits 27, 37, 45, 47, 49, 50, 52 and 54 through 58 attached to the Declaration of Bijan Esfandiari in support of the plaintiffs' opposition to GSK's motion for summary judgment and Exhibits 3, 4, and 5 attached to the Declaration of Richard M. Kapit, M.D. in support of the plaintiffs' opposition to GSK's motion for summary judgment;

IT IS FURTHER ORDERED that the Forsts' motion to strike (Docket #127) be and the same is hereby **DENIED**.

Dated at Milwaukee, Wisconsin, this 29th day of July, 2009.

BY THE COURT:



J.P. Stadtmueller
U.S. District Judge